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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/035,978 | 12/21/2001 | Wilhelmus Quint | INNOG2.001C1 | 4533 |

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

GOLDBERG, JEANINE ANNE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,978

Applicant(s)

QUINT ET AL.

Examiner

Jeanine A Goldberg

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-24, 14 in part is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, in part is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1201; 103.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed November 3, 2003. Currently, claims 1-24 are pending. Claims 1-13, 15-24 and Claims 14, in part have been withdrawn as drawn to non-elected subject matter.
2. This application is in condition for allowance except for the following formal matters:
 - A) Objection to the Abstract.
 - B) Inclusion of non-elected subject matter in claims.
 - C) Inclusion of list of references not cited on IDS.
 - D) SEQ ID NO: 126 and 127 appear to be identical in the sequence listing.
3. Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Election/Restrictions

4. Applicant's election of Group II, SEQ ID NO: 126 in the paper filed November 3, 2003 is acknowledged.

The restriction requirement had set forth the following statement. "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be

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allowable. Currently, there is no generic method or product claim." The response has not argued any single claim is generic. Thus, the claims are restricted to the elected SEQ ID NO: 126.

The response traverses the requirement to select a single species for examination. The response asserts that all 276 nucleic acids are derived from vacA gene and thus share a substantial structural feature essential to the utility. This argument has been thoroughly reviewed, but is not found persuasive because there is no core structure shared between these sequences. Each of the probes and primers appear to be directed to different isolates and strains of the vacA gene. A search of a particular core sequence may not be constructed which is present in all of the claimed sequences such that a single search would be commensurate of all of the sequences. Further, the primers and probes do not appear to be from a single vacA gene, but rather different and divergent vacA genes. Thus a search of fragments of a generic vacA gene is not applicable to the instant sequences. Thus, as written and explained in the specification, each of these probes and primers are patentably distinct from one another and would require a search of 277 nucleic acid sequences to thoroughly search the instant claims in their entirety.

The response also proposes several alternative restriction suggestions. However, for the reasons set forth above, each of these alternatives also fail to share a substantial structural feature. Thus, these alternatives are not deemed appropriate. Furthermore, these alternatives do not include the sequence the response has selected, namely SEQ ID NO: 126. Thus, the examiner is unable to amend the

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restriction/election to ensure that SEQ ID NO: 126 is searched in accordance with applicant's wishes.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. The examiner notes that applicant's have requested rejoinder, however there are no method claims written which encompass using a probe of SEQ ID NO: 126. Thus, rejoinder is not appropriate.

Claims 1-13, 15-24 and Claims 14, in part withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 1-13, 15-24 and Claims 14 in part drawn to an invention nonelected with traverse. A complete reply to this office action must include

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cancellation of nonelected subject matter and claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

5. The drawings are acceptable.

Sequence Rules

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

A) There are numerous sequences throughout the specification which are not identified by SEQ ID NO:.

B) Further, it is unclear whether SEQ ID NO: 126 and 127 are intended to be identical in length and sequence.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate

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paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

For example, the list provided on page 47-48 is has not been considered by the examiner.

Specification

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

9. The abstract of the disclosure is objected to because the abstract is more than 150 words. Correction is required. See MPEP § 608.01(b).

Allowable Subject Matter

10. A search of SEQ ID NO: 126 indicates that the sequence was not known at the time of first filing. A claim drawn to "an isolated vacA polynucleotide sequence of SEQ ID NO: 126" is free of the art and allowable.

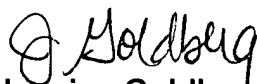
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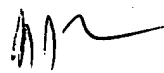
Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571)272-0507


Jeanine Goldberg
Patent Examiner
January 26, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER